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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/286,818	REAM ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,19-22 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19-22 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Appeal Brief filed on 7 June 2006. Upon further consideration, finality of the previous Office action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the phrase "less than a typical amount" is indefinite as a description of medicament dosage, since the "typical amount" varies from medicament to medicament. Thus, one of ordinary skill in the art would receive no guidance as to dosage based on this standard in view of the multitude of drug classes claimed. The specification may offer guidance for some medicaments such as caffeine or aspirin, but does not offer guidance of what a "typical amount" is for the other drug classes claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Gudas, *et. al.* (WO 98/23165).

It is well known in the art that Aspergum® has been commercially available since at least 27 November 1995 (*see* U.S. Patent No. 7,078,052; page 2).

Aspergum® recites:

- the flavors of instant claims 1, 7 and 19 (*see* package, "Inactive Ingredients" under "Drug Facts");
- the chewing of instant claims 1, 7 and 19 (*see* package, "Directions" under "Drug Facts");
- the at least two minutes of chewing of instant claims 2 and 10 (4 hours - *see* package, "Directions" under "Drug Facts");
- the medicament and analgesics of instant claims 1, 4, 7, 8, 9, 19, and 20 (*see* package, "Active Ingredient" under "Drug Facts");
- the chewing of a chewing gum including a medicament at least twice a day of instant claims 5, 12, 19, and 21 (*see* package, "Directions" under "Drug Facts");
- the two pieces of chewing gum chewed at a time of instant claim 22 (*see* package, "Directions" under "Drug Facts"); and
- the blending of the medicament with a base/emulsifier system of instant claim 27 (*see* package, "Inactive Ingredients" under "Drug Facts").

Aspergum® does not recite the use of "less than a typical amount of medicament" as recited in instant claims 1, 7 and 19.

Gudas, et. al. teach a chewing gum containing caffeine (*see* page 2, lines 29-33). The Gudas, et. al. reference teaches a formulation of chewing gum containing a lower

concentration of caffeine (1% - *see* page 22, Table 4) than the instant reference (1.8% - *see* Specification, page 15, line 10). Thus, use of "less than a typical amount of a medicament," in view of the instant Specification, is taught by the Gudas, et. al. reference.

The "blending occurs before the providing" limitation of instant claim 28 would have been obvious to a person of ordinary skill in the art at the time was made because the blending of the medicament with a base/emulsifier system must occur before the final product is ready to be provided to the consumer.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a medicament to a chewing gum, as shown by the product Aspergum® in view of the Gudas, et. al. reference. One of ordinary skill in the art at the time the invention was made would have been motivated to add a medicament to a chewing gum in order to provide relief of various symptoms (*see* Aspergum® package, "Uses" under "Drug Facts").

2. Claims 1-12, 19-22, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Häusler, *et. al.* (U.S. Patent No. 5,922,347).

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose the absorption of a medicament into the systemic system via the oral mucosa, as recited in instant claims 1, 7, and 29.

However, absorption of a medicament in a chewing gum formulation via the oral mucosa was well known in the art at the time the invention was made as shown by Häusler, *et. al.* (*see* col. 2, lines 29-58).

Häusler, *et. al.* explain that this route of administration is beneficial because of rapid absorption and good gastric tolerance (*see* col. 1, lines 40-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a chewing gum formulation with a medicament as a method of delivering the medicament into the systemic system via the oral mucosa, as disclosed by the Aspergum® product in view of Häusler, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to use the oral mucosa as a route of administration because of the beneficial effects of rapid absorption and good gastric tolerance, as taught by Häusler, *et. al.*

3. Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum®.

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose the saliva content of medicament, as recited in instant claims 3, 6, and 11. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable saliva content of medicament through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant saliva content of medicament.

4. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Gudas, *et. al.* (WO 98/23165).

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose adjusting the hydrophilic/lipophilic balance of the medicament, as recited in instant claim 26. However, this procedure was known in the art at the time the invention was made, as taught by Gudas, *et. al.* (see page 18, lines 21-24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the hydrophilic/lipophilic balance of the medicament in a chewing gum formulation, as disclosed by Gudas, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the hydrophilic/lipophilic balance of the medicament in a chewing gum formulation in order to facilitate absorption through the oral mucosa.

Response to Arguments

Applicants' arguments filed on 7 June 2006 have been fully considered but they are not persuasive. Applicants present the same arguments that have been presented before (*see* Remarks filed on 31 October 2005). These arguments have been responded to in an earlier Office action (*see* Office action mailed on 11 January 2006).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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